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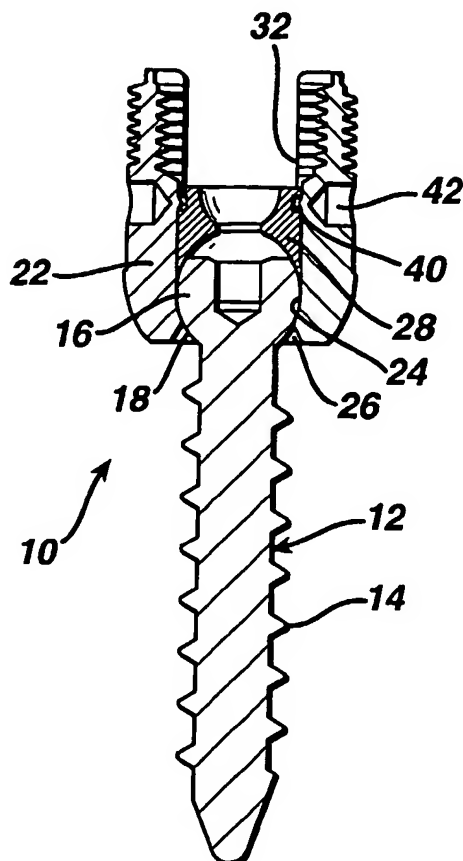
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(54) Title: **POLYAXIAL SCREW WITH IMPROVED LOCKING**



(57) Abstract: A polyaxial pedicle screw assembly incorporates a concave portion on a receiver which mates with a convex surface on a head of the screw to form a ball joint. The radius of at least a portion of the concave surface is less than a radius of the mating convex portion whereby to create an interference fit.



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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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Polyaxial Screw with Improved Locking

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Field of the Invention

The present invention relates to a polyaxial pedicle
10 screw.

Background

Polyaxial pedicle screws such as disclosed in Biedermann
15 et al.'s US Patent No. 5,443,467, incorporated herein by
reference, are used for connecting vertebrae to rods in spinal
surgery. They incorporate a ball joint at the connection to
the rod to allow the surgeon some flexibility in placing the
screws. Tightening a nut on the screw compresses the ball
20 joint components to lock the angular position of the ball
joint.

Summary of the Invention

25 The present invention, improves the locking force
achieved when locking the ball joint.

A pedicle screw assembly according to the present
invention comprises a screw having a head with a convex
30 portion and a receiver receiving the head. The receiver also
receives an elongate member, such as a spinal fixation rod.
The receiver has a concave portion which has a radius of
curvature which is less than a radius of curvature of the
convex portion of the head whereby to create an interference
35 fit between the convex portion of the head and the concave
portion of the receiver.

Preferably, a nut on the receiver compresses the convex portion of the head into the concave portion of the receiver.

In one convenient orientation, the receiver comprises a U-shaped portion for receiving the elongated member.

Preferably, the concave portion of the receiver is formed of titanium. Although other shapes may be employed, in one preferred orientation each of the concave portion and convex portion have a spherical shape. Any shapes which allow

rotational freedom of the head and receiver prior to engagement of the surfaces would suffice.

In one preferred embodiment the screw comprises an elongated shank having bone threads thereon and the head located at one end thereof and the receiver comprises a body having an aperture therethrough for receiving the shank and having the concave portion located at the aperture. The receiver further comprises a channel therethrough opposite the aperture, the channel receiving the elongate member.

The pedicle screw can further comprises a compression member between the elongate member and the head; the head having a second convex portion facing the compression member and the compression member having a second concave portion facing the head, the second concave portion having a radius of curvature less than a radius of curvature of the second convex portion whereby to create an interference fit between the head and the pressure member.

The difference in the radius of curvature between the convex and concave portions in one embodiment is about 0.05 mm.

Brief Description of the Drawings

FIG. 1 is a cutaway view of a pedicle screw according to the present invention;

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FIG. 2 is an additional cutaway view of the screw of FIG. 1 with rod and locking nuts removed for clarity; and

FIG. 3 is a detailed cutaway view of a portion of the receiver of FIG. 1.

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Detailed Description

FIGS. 1 and 2 illustrates a polyaxial screw assembly according to the present invention. It comprises a screw 12 having cancellous threads 14 for insertion into the cancellous bone of a vertebra, especially through the pedicle. A spherically shaped head 16 has a convex surface 18 and a tool recess 20 for receiving a hex driver or other tool (not shown). The head 16 is received within a tubular receiver 22 having an internal concave surface 24 and an adjacent opening 26. The convex surface 18 of the head 16 mates with the concave surface 24. The opening 26 is smaller than the head 16 so that the screw 12 can project out of the opening 26 without falling out of the receiver 22.

25

A pressure disk 28 sits atop the head 26 and has a surface 30 of mating shape to that of the head 26. The receiver also has a U-shaped portion 32 which receives an elongated rod 34. The rod 34 is used to connect adjoining vertebrae as is known in the art. An internal nut 36 and external nut 38 compress the rod 34 against the pressure disk 28 which in turn compresses the head convex portion 18 into the receiver concave portion 24 and locks the angular position of the receiver 22 with respect to the screw 12.

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The pressure disk 28 preferably has a lateral indentation 40 into which a material on the receiver 22 is swaged 42 to hold the pressure disk 28 within the receiver 22 but allow
5 some movement therein.

FIG. 3 illustrates the feature which improves the locking of the receiver 22 with respect to the screw 12 over prior similar screw assemblies. The concave surface 26 has a
10 slightly smaller radius of curvature than does the convex surface 18 so that when the two are compressed together, the material deforms somewhat to allow the surfaces to mate in an interference fit and thus enhances the grip between the surfaces.

15 Tests of the deflection of the screw 12 under a torque load versus a prior screw show a significant decrease in deflection versus the prior screw, thus less slippage and better locking. Tables 1 and show the results of tests of
20 screws with and without the interference fit. The seven screws in Table 1 were formed of stainless steel and the seven screws in Table 2 of titanium. The screws labeled Magnum contain the interference fit and the others did not. The screws are of similar dimensions; the numbers listed after the
25 screw refer to the rod size. The tests consist of locking the screws to a uniform torque and then applying a lateral force to the screw 12 to induce a torque at the head 16. The load at an offset of 0.5mm and the stiffness were assessed for each sample. The screws with the interference fit of the present
30 invention exhibited gains in both parameters.

Table 1

Static Cantilever Beam Evaluation
 Moss-Miami (no interference fit) vs.
 Moss-Miami Magnum (interference fit)

5

Stainless Steel

Specimen	1	2	3	4	5	6	7	Avg	Std Dev
	Load at Offset 0.5mm (Kn)								
Moss-Miami 6.0	0.2107	0.2188	0.2121	0.2926	0.2483	0.2349	0.3571	0.25	0.05
Moss-Miami Magnum 6.34	0.2470	0.3101	0.3678	0.2752	0.2926	0.3074	0.2618	0.29	0.04
	Stiffness N/mm								
Moss-Miami 6.0	602.2	459.8	229.9	594.3	245.8	538.8	570.8	463.1	160.99
Moss-Miami Magnum 6.34	637.0	705.2	627.8	611.4	753.2	721.1	689.8	677.9	53.27

Table 2

Static Cantilever Beam Evaluation
 Moss-Miami (no interference fit) vs.
 Moss-Miami Magnum (interference fit)

10

Titanium

Specimen	1	2	3	4	5	6	7	Avg	Std Dev
	Load at Offset 0.5mm (Kn)								
Moss-Miami 6.0	0.2859	0.3047	0.2389	0.3074	0.2959	0.2403	0.3302	0.28	0.04
Moss-Miami Magnum 6.34	0.3730	0.4495	0.4502	0.4929	0.5348	0.5342	0.5114	0.48	0.06
	Stiffness N/mm								
Moss-Miami 6.0	451.9	404.9	293.3	467.7	404.1	316.9	396.4	390.7	64.58
Moss-Miami Magnum 6.34	707.4	572.1	573.9	526.6	580.0	578.7	517.1	584.5	58.38

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In one preferred embodiment, the head convex surface 18
 would have a diameter of 6.995 mm and the mating receiver

concave surface 24 would have a diameter of 6.88 mm. Similar interference dimensions could also be applied to the mating interface of the pressure disk surface 30 and the head 16.

- 5 While the invention has been described with regard to a particular embodiment thereof, those skilled in the art will understand, of course, that the invention is not limited thereto since modifications can be made by those skilled in the art, particularly in light of the foregoing teachings.
- 10 Reasonable variation and modification are possible within the foregoing disclosure of the invention without the departing from the spirit of the invention.

IN THE CLAIMS

1. A pedicle screw assembly comprising:

a screw having a head with a convex portion;

5 a receiver receiving the head and an elongated member; and

the receiver having a concave portion, the concave portion having a radius of curvature which is less than a radius of curvature of the convex portion of the head whereby
10 to create an interference fit between the convex portion of the head and the concave portion of the receiver.

2. A pedicle screw assembly according to claim 1 and further comprising a nut on the receiver which compresses the
15 convex portion of the head into the concave portion of the receiver.

3. A pedicle screw assembly according to claim 2 wherein the receiver comprises a U-shaped portion for
20 receiving the elongated member.

4. A pedicle screw assembly according to claim 2 wherein the concave portion of the receiver is formed of titanium.
25

5. A pedicle screw assembly according to claim 1 wherein each of the concave portion and convex portion have a spherical shape.

30 6. A pedicle screw assembly according to claim 1 wherein the screw comprises an elongated shank having bone threads thereon and the head located at one end thereof;

wherein the receiver comprises a body having an aperture therethrough for receiving the shank and having the concave portion located at the aperture;

wherein the receiver further comprises a channel
5 therethrough opposite the aperture, the channel receiving the elongate member.

7. A pedicle screw according to claim 6 and further comprising a compression member between the elongate member
10 and the head; the head having a second convex portion facing the compression member and the compression member having a second concave portion facing the head, the second concave portion having a radius of curvature less than a radius of curvature of the second convex portion whereby to create an
15 interference fit between the head and the pressure member.

8. A pedicle screw according to claim 1 wherein the radius of curvature of the concave portion is about 0.05 mm smaller than the radius of curvature of the convex portion.

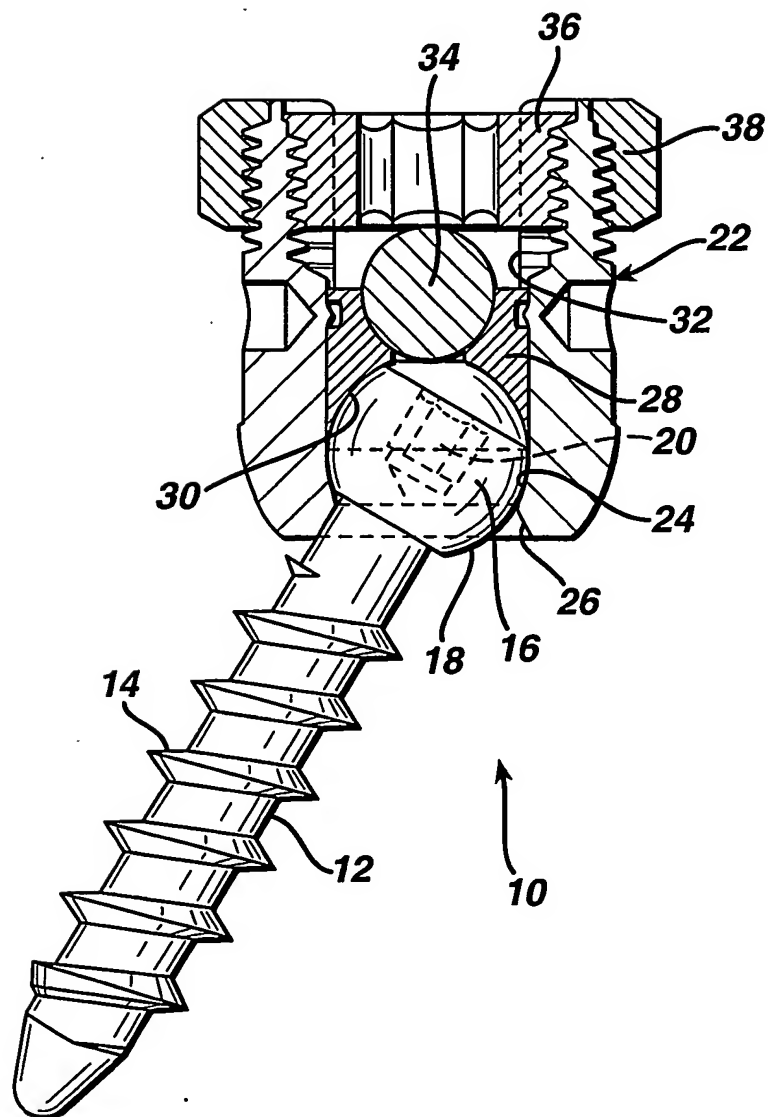
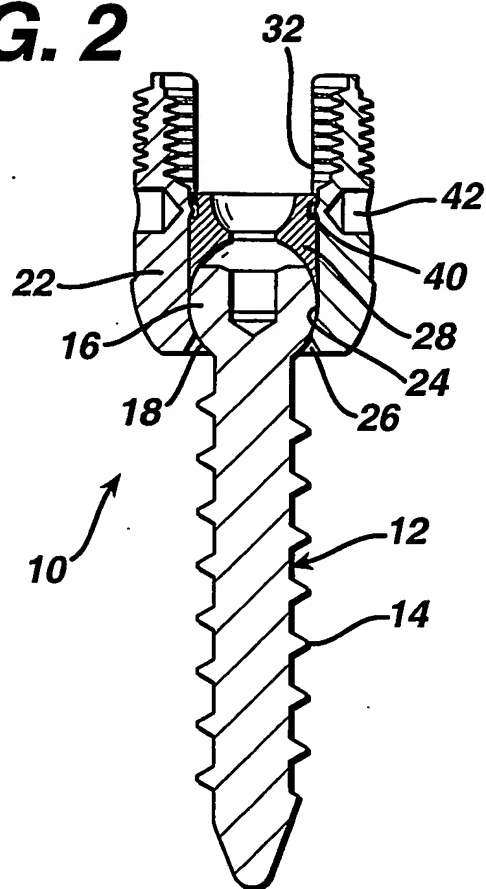
FIG. 1

FIG. 2**FIG. 3**